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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,400	06/04/2001	Werner G. Kuhr	407T-894701US	5307

22798 7590 10/07/2004

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/874,400

Applicant(s)

KUHR ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 July 2004 has been entered.

#### ***Status of the Claims***

2. This action is in response to papers filed 23 July 2004 in which claim 1 was amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 26 June 2003 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-21 are under prosecution.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-12 are each indefinite because it is vague and indefinite what is meant by the phrase "less than about 100 (500) $\mu$ m". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term "about" which implies that values above and below the claimed value are permitted. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification. The phrase "less than about" is deemed equally indefinite.

Claims 13 is indefinite for the recitation "said two or more analytes" because the recitation lacks proper antecedent basis in Claim 1.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 10-17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998).

Regarding Claim 1, Muscate et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed therein differing first and second analyte-specific binding partners located in different regions of the channel (Column 3, lines 18-48), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Abstract; Column 15, lines 6-20; and Column 18, lines 57-59 "UV-transmitting window").

Regarding Claim 2, Muscate et al disclose the method wherein the analytes are not labeled (e.g. Example D1).

Regarding Claim 3, Muscate et al disclose the method wherein the channel is a capillary tube (Abstract).

Regarding Claim 4, Muscate et al disclose the method wherein the capillary tube is a capillary electrophoresis tube (Column 14, lines 3-10).

Regarding Claim 5, Muscate et al disclose the method wherein the capillary is an etched surface (Column 13, line 66-Column 14, line 1).

Regarding Claim 6, Muscate et al disclose the method wherein the channel is etched in glass (Column 13, lines 62-67).

Regarding Claim 10-12, Muscate et al disclose the method wherein the channel has a cross-sectional diameter and width of less than 100 $\mu$ m (Column 13, lines 55-56).

Regarding Claim 13, Muscate et al disclose the method wherein the analytes comprise at least three different analytes (i.e. 10 different analyte-specific receptors, Column 3, lines 45-48).

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Regarding Claim 14, Muscate et al disclose the method wherein the binding partners are antibodies, binding proteins or nucleic acids (Column 6, lines 56-65).

Regarding Claim 15, Muscate et al disclose the method wherein the binding partners are nucleic acids (Column 6, lines 56-65).

Regarding Claim 16, Muscate et al disclose the method wherein the passing a fluid is induced by a pressure difference (Column 14, lines 44-48).

Regarding Claim 17, Muscate et al disclose the method wherein the passing of fluid comprises electro osmotic flow (Column 14, lines 38-44).

Regarding Claim 19, Muscate et al disclose the method wherein detecting comprises absorbance spectroscopy (Column 14, lines 30-34).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998) in view of Wainright et al (U.S. Patent No. 6,306,273, filed 13 April 1999).

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Regarding Claim 7-8, Muscate et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed therein differing first and second analyte-specific binding partners located in different regions of the channel (Column 3, lines 18-48), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Abstract; Column 15, lines 6-20; and Column 18, lines 57-59 "UV-transmitting window").

Muscate et al further teach numerous and various surfaces for the channels are known and useful in their method (Column 13, line 62-Column 14, line 2) but they do not specifically teach ceramic or plastic. However, surfaces for channel construction comprising plastic and/or ceramic were well known in the art at the time the claimed invention was made as taught by Wainright et al (Column 23, lines 65-67) who specifically the composition is selected based on particular use, economic concerns, solvent compatibility, optical clarity, color, mechanical strength, dielectric properties and etc (Column 24, lines 1-7). They further teach plastic is preferred for disposable devices due to their low cost and ease of manufacture (Column 24, lines 7-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the surface composition of Wainright et al to the assay device of Muscate et al and to select the claimed plastic or ceramic surface based on "particular use" as taught by Wainright (Column 23, line 65-Column 24, line 7). It would have been further obvious to specifically select a plastic surface based on economy and ease of manufacture as taught by Wainright (Column 24, lines 7-14).

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9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998) in view of Yager (U.S. Patent No. 6,007,775, issued 28 December 1999).

Regarding Claim 9, Muscate et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed therein differing first and second analyte-specific binding partners located in different regions of the channel (Column 3, lines 18-48), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Abstract; Column 15, lines 6-20; and Column 18, lines 57-59 "UV-transmitting window").

Muscate et al are silent regarding a cross-sectional area that provides a Reynold's number of less than about 1. However, it was well known in the art at the time the claimed invention was made that channels having a Reynold's number of less than about 1 were desirable because a low Reynold's number provides laminar flow (see Yager, Column 4, line 59-Column 5, line 5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cross-sectional area of Muscate's channels to provide a Reynold's number of less than about 1 for the obvious benefits of laminar flow i.e. facilitates analyte diffusion and detection as taught by Yager (Column 4, line 59-Column 5, line 14).

10. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998) in view of Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998).

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Regarding Claim 18, Muscate et al disclose the method of Claim 1 is useful for disease-specific assays e.g. immunoassays, enzyme assays and gene-specific assays (Column 16, lines 3-20) but they are silent regarding the source of sample. However, the claimed sources of blood, plasma, serum, urine, oral fluid, cerebrospinal fluid and lymph are all well known sample routinely used in immunoassays, enzyme assays and gene-specific assays as taught by Muller et al (Column 10, lines 38-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to derive samples from the claimed sources to perform the immunoassays, enzyme assays and gene-specific assays of Muscate et al based on the routine practice of performing such assays on those samples as taught by Muller et al (Column 10, lines 38-47).

Regarding Claim 21, Muscate et al specifically teach their method is highly sensitive (Column 15, lines 47-51) and Muller et al teach a very similar method wherein their analyte concentration provides for detection of multiple analytes in a sample with high sensitivity and without prior amplification (Column 3, lines 9-24). The teachings of Muscate et al and Muller et al clearly suggest detection of analytes at a concentration of less than  $10^{-9}\text{M}$ . Hence, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that to apply the methods of Muscate et al and Muller to detect analytes at the claimed concentration based on their teachings of high sensitivity.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998) in view of Kuhr et al (U.S. Patent No. 5,958,215, issued 28 September 1999).

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Regarding Claim 20, Muscate et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed therein differing first and second analyte-specific binding partners located in different regions of the channel (Column 3, lines 18-48), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Abstract; Column 15, lines 6-20; and Column 18, lines 57-59 "UV-transmitting window") wherein the detection uses various techniques known in the art (Column 14, lines 30-34) but they do not teach detection using sinusoidal voltammetry.

However, sinusoidal voltammetry detection was well known in the art at the time the claimed invention was made as taught by Kuhr et al who specifically teach sinusoidal voltammetry detection is more sensitive than traditional methods (Column 3, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply sinusoidal voltammetry to the detection step of Muscate et al for the expected benefit of improved detection sensitivity as taught by Kuhr et al (Column 3, lines 10-25).

### **Conclusion**

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
October 6, 2004